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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA
FRESNO DIVISION

The United States of America, and The State of California *ex rel.* Hector Miranda, MD, and **Erin Craig,**

Relators,

Plaintiffs,

v.

Robert Gonzalez Salazar, MD,

Defendant.

No. 1:20-cv-1257-AWI-SKO

Complaint for Violations of the Federal and California False Claims Acts, 31 U.S.C. § 3729 *et seq.* and Cal. Gov. Code § 12650 *et seq.*

Jury Trial Demanded

Lodged Under Seal Pursuant to 31 U.S.C. §§ 3730(b)(2) and (3).

1. Medical necessity sometimes justifies the risks of surgically implanting a pump in a patient to inject opioids or other painkillers directly into a patient's spine, and then, usually months later, refilling and reprogramming the pump. Defendant Dr. Salazar submits Medicare claims for pump refills and reprogramming more frequently than medically necessary. If he is performing the procedures he claims, then he is unnecessarily risking patient harm.

I. Jurisdiction, Venue, and Parties

2. This Court has jurisdiction under 31 U.S.C. § 3732 and 28 U.S.C. § 1345. Jurisdiction over the state law claims arises under 31 U.S.C. § 3732(b) (jurisdiction over state claims arising from the same transaction or occurrence as an action under the federal FCA), and 28 U.S.C. § 1367(a) (supplemental jurisdiction).

3. This Court has personal jurisdiction over Defendant Salazar because he transacts business and can be found in this district and committed acts within this district that violate 31 U.S.C. § 3729. 31 U.S.C. § 3732(a).

4. Upon information and belief, none of the jurisdictional bars in the FCA, 31 U.S.C. § 3730(e) apply to this action.

5. Venue is proper in this district under 31 U.S.C. § 3732(a) and 28 U.S.C. §1391(b) and (c) because Defendant resides and/or transacts business in this district and has committed acts within this district that violate 31 U.S.C. § 3729. Section 3732(a) further provides for nationwide service of process.

6. Relators complied with all procedural requirements of 31 U.S.C. §3730(b)(2).

7. **Relator Hector Miranda, M.D.,** is competent to opine on the procedures discussed below. Dr. Miranda is a triple board-certified physician. He is board certified in Physical Medicine & Rehabilitation, Pain Medicine, and Brain Injury Medicine. He is also a certified life care planner. Dr. Miranda is a graduate of the University of Puerto Rico School of Medicine. He completed his residency in Physical Medicine and Rehabilitation at the University of Miami Miller School of Medicine, and a fellowship in Pain Medicine at Beth Israel Medical Center in New York. He is a diplomate of the American Board of Physical Medicine and Rehabilitation.

8. **Relator Erin Craig**, B.A. (Mathematics), M.S. (Data Science), has worked as a Data Scientist, using electronic health records to improve healthcare and hospital care, and investigating healthcare fraud.

9. With respect to each allegation herein made upon information and belief, Relators have, based upon their knowledge, experience, and supporting data, a reasoned factual basis to make the allegations but lack complete details of it. While Relators have significant evidence of the fraud alleged herein (the details of which follow), much of the documentary evidence necessary to prove the allegations in this Complaint is in the possession of the Defendant and the United States.

10. **Defendant Robert Gonzalez Salazar**, M.D., NPI 1104841253, California license G42244, practices medicine in Fresno in this district.

11. The American Board of Anesthesiology shows Defendant has a "primary certification" issued in 1985 and is certified indefinitely. The Board notes "Primary

certificates in anesthesiology issued prior to January 1, 2000 are not time-limited and do not have an expiration date."

12. On information and belief, Dr. Salazar has medical staff privileges at Saint Agnes Hospital in Fresno.

13. In 2017, Medicare Part B paid Dr. Salazar $1,214,746 for more than 11,449 claimed procedures.

II. The False Claims Act and Medicare

A. False Claims Act

14. The Federal False Claims Act is the federal government's primary tool to recover losses due to fraud and abuse by those seeking payment from the United States. *See*

15. S. Rep. No. 345, 99 Cong. 2d Sess. at 2 (1986), reprinted in 1986 U.S.C.C.A.N. 5266.

16. The Act prohibits the submission of false or fraudulent claims and false statements to obtain or keep federal money. 31 U.S.C. § 3729(a)(1).

17. Under the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), civil penalties were adjusted from $ 5,500 to $ 11,000 for violations occurring on or after September 29, 1999. For violations occurring after November 1, 2015, Department of Justice (DOJ) announced increased penalties to between $10,781 and $21,562 per fraudulent claim.

18. California patterned the California False Claims Act, California Government Code §§ 12650 *et seq.* ("CFCA"), on the federal statutory scheme.

19. The requirements for state liability are substantially the same as for federal liability. *See* Cal. Govt. Code § 12651(a)(1-3, 7).

20. Defendant agreed to comply with California's Welfare and Institutions Code pursuant to its Medi-Cal provider agreement.

21. The terms "knowing" and "knowingly" "mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). No proof of specific intent to defraud is required. 31 U.S.C. § 3729(b)(1)(B). *See* Cal. Govt. Code § 12650(b).

B. Medicare and Medicaid

22. Medicare is a third-party reimbursement program that underwrites medical expenses of the elderly and the disabled. 42 U.S.C.§§ 1395 *et seq*. The Medicare claims in this case arise under Medicare Part B, which generally covers physician services, including medical and surgical treatment, and outpatient treatment and diagnosis. Part B, 42 U.S.C. §§ 1395j *et seq*.; 1395l (payment of benefits).

23. Medicaid is a medical assistance program for indigent and other needy people that is financed by joint federal and state funding and is administered by the states according to federal regulations, oversight, and enforcement. 42 U.S.C. §§ 1396 *et seq*. Each state implements its version of Medicaid, such as California's Medi-Cal, according to a State Plan approved by HHS. Within broad federal regulatory and policy guidelines (*see* 42 C.F.R. § 430 *et seq*., and CMS publications), the states determine who is Medicaid-eligible, what services are covered, and how much to reimburse healthcare providers. The

states, through intermediaries, also receive healthcare provider claims for program reimbursements, evaluate those claims, make payments to healthcare providers, and present the claims to HHS/CMS for reimbursement of the federal government's share.

24. These government programs do not pay for every medical service that a doctor may prescribe, recommend, or perform. Although providers can receive reimbursement for their services, the programs only reimburse for services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). *See also* 42 C.F.R. § 411.15(k)(1).

25. Medicare further requires that services be provided economically and that they are supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required by a reviewing quality improvement organization in the exercise of its duties and responsibilities. 42 U.S.C. § 1320c-5. *See generally, Corkill v. Shalala*, 109 F.3d 1348, 1351 (9th Cir. 1996) (finding § 1320c-5 violation where physician failed to document medical necessity and did not adequately describe patients' symptoms or diagnoses or adequately explain decisions).

26. Services performed for no reason other than obtaining a profit are considered medically unnecessary and are not reimbursable by government healthcare programs. *See e.g., United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp. 2d 35, 41-42 (D. Mass. 2000).

27. CMS has final authority over what services are "reasonable and necessary" and makes such determinations in several ways. First, CMS can make a "national coverage

determination," which determines "whether or not a particular item or service is covered nationally." 42 U.S.C. § 1395y(l)(6)(A). Second, the administrative contractors responsible for reviewing Medicare claims can make "local coverage determination[s]," which determine whether a treatment is covered for claims within that contractor's responsibility. *Id.* §§ 1395y(l)(6)(B), 1395ff(f)(2)(B). Third, contractors can make determinations on a claim-by-claim basis. *See id.* § 1395ff(a)(1)(A). Further, CMS consults "the advice of medical consultants," the "accepted standards of medical practice," and, when applicable, the "medical circumstances of the individual case." CMS, Medicare Benefit Policy Manual, Ch. 15 § 50.4.3 (2016).

28. Physicians must enroll in the Medicare program to be eligible to receive Medicare payment for covered services provided to Medicare beneficiaries. 42 C.F.R. § 424.505.

29. Physicians and other qualified medical providers play a key role in enforcing the "reasonable and necessary" requirement by certifying that the services provided were "medically necessary" and "medically indicated and necessary to the health of the patient." 42 C.F.R. § 424.10(a), *see also* 42 U.S.C. § 1395f(a)(2)-(3) (Part A); *id.* § 1395n(a)(2) (Part B). Typically, this certification occurs on CMS Form, 1500 Health Insurance Claim Form, or its electronic equivalent. 42 C.F.R. § 424.32 (Basic requirements for all claims). The form requires the physician to certify that the services provided were "medically necessary" and "medically indicated and necessary to the health of the patient."

30. If the physician certifies the necessity of the procedure, then the claim will likely to be paid because Medicare claims processing is largely an automated process.

31. At all times relevant to this action, Defendant submitted, or caused to be submitted, the electronic equivalent of Form 1500 to CMS and California for reimbursement for services.

32. Form 1500 requires the submitting healthcare provider to include various fields of information prior to reimbursement, including: the date(s) of service; a code for the service(s) provided known as a "Current Procedural Terminology Code" or "CPT Code"; and the rendering healthcare provider's national identification number ("National Provider Identifier" or "NPI") and signature.

33. According to Form 1500's instructions, a provider's signature certifies "that services shown on [the Form 1500] were medically indicated and necessary for the health of the patient and were personally furnished by [the provider] or were furnished incident to [his/her] professional service by [his/her] employee under [his/her] immediate personal supervision."

34. Providers, such as Defendant, submit or cause the submission of claims to Medicare by transmitting them to a private carrier or a Medicare Administrative Contractor ("MAC"), which processes the claims on behalf of HHS/CMS.

35. All healthcare providers that submit claims electronically to CMS or to CMS MACs must certify in their application that they "will submit claims that are accurate, complete, and truthful," must acknowledge that "all claims will be paid from Federal funds, that the submission of such claims is a claim for payment under the Medicare program, and that anyone who misrepresents or falsifies or causes to be misrepresented or falsified any record or other information relating to that claim that is required pursuant to

this agreement may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law." *See* Medicare Claims Processing Manual, § 30.2.A.

36. Similar rules apply to Medicaid healthcare providers.

37. Medicare, Medicaid, and related government rules and policies require healthcare providers to contemporaneously create and maintain accurate medical records to support the providers' claims for reimbursement. *See e.g.*, CMS MLN Matters Number: SE1022 ("Providers/suppliers should maintain a medical record for each Medicare beneficiary that is their patient. Remember that medical records must be accurately written, promptly completed, accessible, properly filed and retained.")

38. Courts have looked for guidance to the CMS Medicare Program Integrity Manual and its elucidation of what is "reasonable and necessary." The Manual includes at § 13.3 (incorporating § 13.5.1's definition of "reasonable and necessary" for individual claim determinations), among these definitional requirements, that the service is:

- Safe and effective;
- Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
- Furnished in a setting appropriate to the patient's medical needs and condition;
- One that meets, but does not exceed, the patient's medical need; and
- At least as beneficial as an existing and available medically appropriate alternative.

39. Additionally, § 13.7.1 governs "Evidence Supporting LCDs." While § 13.3 does not specifically link to § 13.7.1, it looks to general acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:

- Scientific data or research studies published in peer-reviewed medical journals;

- Consensus of expert medical opinion (i.e., recognized authorities in the field); or
- Medical opinion derived from consultations with medical associations or other health care experts.

40. In addition to medical necessity and reasonableness, healthcare providers who submit Medicare claims must certify, among other things, that all statements in the claim are true, accurate, and complete to the best of the provider's knowledge; that no material fact has been omitted; that the provider is bound by all rules, regulations, policies, standards, fee codes and procedures.

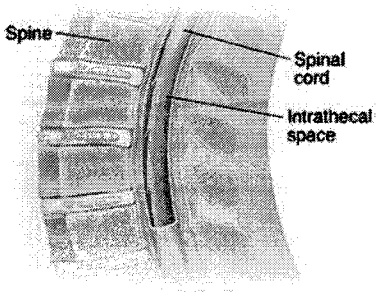
41. When submitting a claim for reimbursement, the claimant must provide documentation that supports the claim. Appropriate documentation typically involves correctly coding certain services to enable the Government to reimburse the healthcare provider at the proper rate.

III. Defendant's Fraudulent Conduct

A. Unnecessary Spinal Pump Refills, CPTs 62368 and 62370

i. Overview of intrathecal (spinal) pain pumps.

42. When a patient's pain cannot be adequately managed with medicines taken orally physicians consider surgically implanting pumps under the skin and adjacent to the spine to deliver medications through a catheter directly into the spinal fluid.



43. This is called *intrathecal* delivery (or administration). The *theca* is a tube or sheath that surrounds the spinal cord. The pumps are often referenced as "ITP" for Intrathecal Pumps.

44. Properly administered ITP provides patients with constant drug delivery which should provide pain relief at lower doses than with oral pain medications. ITP can also minimize some side effects of oral medications as the intrathecal doses are much less than the doses needed to provide the same pain relief when taking the medications by mouth.

45. However, significant side effects and complications can occur with implantation and management of these devices.[1] For this reason, this approach is medically reasonable only after less invasive approaches have failed. *See generally*, Local Coverage Determination, A55239, *Implantable Infusion Pumps for Chronic Pain* (including among the requirements for reimbursement "The patient's medical condition must require the use of an infusion pump for pain relief due to failure of other treatment modalities.")

46. Risks associated with ITPs and ITP administration include death, spinal cord injury and nerve injury, cerebrospinal fluid leaks, drug delivery overdose, seizures, opiate drug withdrawal syndrome, weight gain, and systemic and local infections.

47. In general, anesthetics must be carefully administered because of their potentially toxic effects. Local toxic effects include prolonged anesthesia and paresthesia (an abnormal tingling, pricking, chilling, burning, or numb sensation) which may become irreversible. Systemic toxicity often involves the central nervous system or the cardiovascular system and may cause death or permanent brain dysfunction. Anesthetic agents can be toxic if administered inappropriately and, occasionally, even when properly administered.

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[1] https://academic.oup.com/painmedicine/article/9/suppl_1/S102/1824327

48. Implanted pumps require healthcare providers to periodically refill the pumps with medication and to reprogram the rate and amount of drugs delivered by the pump.

49. Refilling and reprogramming the pumps carry additional risks.

50. Unnecessarily inserting needles to inject medications risks patient harm including:

- Puncture of a blood vessel (intravascular injection).
- Infections around the injection location. Bacterial infection may cause cellulitis (subcutaneous fatty tissue inflammation) or abscesses.
- Inadvertent administration outside the pump itself, which can cause systemic symptoms, such as drug overdose, which can lead to respiratory failure and/or heart attacks.
- Adverse reactions to injected medications, such as possible allergic reactions.

51. In addition to routine complications that occur with any surgical procedure, implantation and refill of an ITP have significant risks, including death. In addition to the risks above, the pumps, catheters, and drugs infused in the pumps each carry their own risks during ITP refills and reprogramming. These risks include:

- If the wrong drug volume and concentration inside the catheter or the pump is programmed during the pump implantation process, a patient could overdose and die, or could be underdosed and have withdrawal syndrome, which can lead to death, depending on a patient's comorbidities.
- If the pump is improperly programmed during the refill process, the patient could overdose and die.
- If the medication is accidentally injected outside the pump, rather than into the pump, the medication would be delivered systemically and could cause drug overdose and death.
- Catheters that link the pump to the spine can fracture, kink, and migrate resulting in immediate discontinuation of analgesia and precipitation of withdrawal.

- *Pump dumps* or release of large concentration of analgesics acutely could lead to overdose and death.
- Various drugs have been associated with the formation of granulomas, or inflammatory masses at the tip of the catheters, thereby interfering with steadiness of drug delivery and cause overdose and/or withdrawal syndrome.
- Centrally administered opioids and other drugs can lead to numerous side effects, including the need for higher doses over time.

52. Other potential complications related to ITPs are catheter clogging, catheter fractures, and scar tissue around the catheter tip—all conditions that can alter the programmed rate of delivery of the medications and cause serious complications like overdose or under-dosing (causing withdrawal syndrome).

53. Elderly patients, such as most Medicare patients, face even more risks, especially those with comorbidities such as:

- patients on blood-thinning medications,
- patients with active infections,
- patients with poorly controlled diabetes,
- patients with heart disease, and
- overweight patients.

54. Although intrathecal pain pumps (ITP) can be performed in private practice medical settings, higher patient volume settings are often done in Pain Fellowship programs at teaching institutions. The reason for this is that pain management through ITP's, including their refills and reprogramming, is a complex pain management procedure fraught with many risks and complications. Hospitalization may be necessary to address complications associated with spinal pumps. Hospitals and teaching institutions

have the trained staff and, importantly, they also tend to have 24/7 on-call staff who can manage complications of such pumps.

55. The accuracy of the pumps' software calculations depends on using the approved medicine, medicine concentration, and medicine characteristics. For example, if there is more than one medicine in the pump reservoir, the pump software can only calculate the dose based on the infusion rate of a single medicine.[2]

56. The refill codes relevant to this Complaint are CPTs 62368 and 62370.

57. CPT 62368 is the "Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with programming (*but no refill*).

58. CPT 62370 is identical to 62368 except as of 2012 it requires a refill and is noted as "requiring physician's skill because of difficult access or other medical issues or complex reprogramming of his pump."

59. In Relator Dr. Miranda's experience, ITPs usually get refilled every 3 months. Having a high volume of patients get pump refills more often than every 3 months is unusual.

60. Medicare part B data is consistent with Relators experience. For example, in 2017, Medicare part B providers claimed an average of 2.87 procedures per patient for CPT code 62370, meaning that patients receive an average of fewer than three refills during a

[2] https://www.fda.gov/news-events/press-announcements/fda-alerts-doctors-patients-about-risk-complications-when-certain-implanted-pumps-are-used-deliver

year. Similarly, for CPT code 62368, Medicare part B providers averaged 2.46 claims per year.

61. At least two types of patients require more frequent refills. But these are infrequent exceptions. One exception is patients who receive ziconotide (Prialt). But ziconotide is rarely used and its indications are more restricted because of its risky and dangerous side effects. Dr. Miranda can recall having treated only four patients in his career who require ziconotide. The other exception involves patients who have a high rate of delivery in combination with high doses due to the severity of their pain. These two patient populations are not the norm.

ii. Dr. Salazar's high volume repeat business.

62. Dr. Salazar claims an unusually high volume of repetitions per patient, especially for the more lucrative refill code, CPT 62370. Compared to the Medicare part B national average of 2.87, Dr. Salazar claims CPT 62370, on average three times as often.

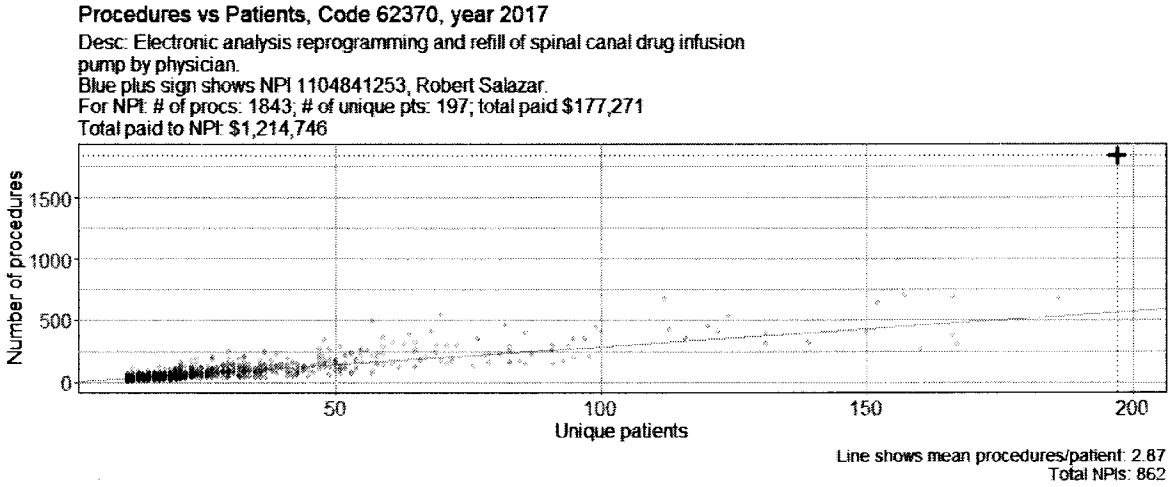
CPT 62370

year	procedures	patients	procedures per pt.
2014	2,150	257	8.57
2015	1,958	232	8.4
2016	1,159	203	5.7
2017	1,843	197	9.3

CPT62368

year	procedures	patients	procedures per pt.
2014	525	118	4.4
2015	420	95	4.4
2016	195	60	3.2
2017	275	64	4.3

63. The graphic below shows Dr. Salazar's claimed repetitions in 2017 compared to the 862 other NPI's (physicians) claim this procedure.



64. Dr. Salazar performs CPT 62370 more often than any other provider in the nation.

62370		
Year	Amt paid	National rank
2014	$ 219,294	1
2015	202,483	1
2016	118,214	1 [3]
2017	177,271	1

65. For CPT 62368, he is among the top 10 providers in the nation in terms of volume of claiming this procedure.

62368		
Year	Amt paid	National rank
2014	$ 23,860	1
2015	19,134	2
2016	8,419	13 [4]
2017	11,397	4

66. Having a high volume of patients with such pump refills and reprogramming, increases the likelihood of the above-mentioned complications.

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[3] William Johncox, NPI 1023124278, who shares space with Dr. Salazar, was the second highest claimant in 2016.

[4] William Johncox, who shares space with Dr. Salazar, was the ninth highest claimant.

67. With respect to the procedures discussed above claimed by Defendant, Relator Dr. Miranda concluded, based on his experience and knowledge:

- There is no subspecialty limited to patients who require more frequent ITP refills or reprogramming.
- There is no subspecialty limited to patients who require ziconotide (Prialt), a medicine which requires more frequent refills.
- It is medically reasonable and appropriate for a pain physician to routinely address pain through non-invasive approaches and to proceed with invasive riskier ITP only after less invasive approaches and medications have failed.
- It is medically unreasonable and unnecessary, and below the standards of professional conduct, to routinely puncture patients' spines with a permanent intrathecal catheter and implant a pump for routine pain management.
- There is no "cluster" of symptoms or diagnoses that would make this volume of repeat refills medically reasonable or necessary more often in California then elsewhere in the country.
- *For most patients, it is medically unreasonable and unnecessary to routinely refill and reprogram pumps at the rate claimed by Defendant.*

68. Based on Relators' experience and expertise in pain management and healthcare data analytics, Relators have determined that many of Defendant's claims are false.

B. Unnecessary Ultrasound Guidance Imaging, CPT 76942

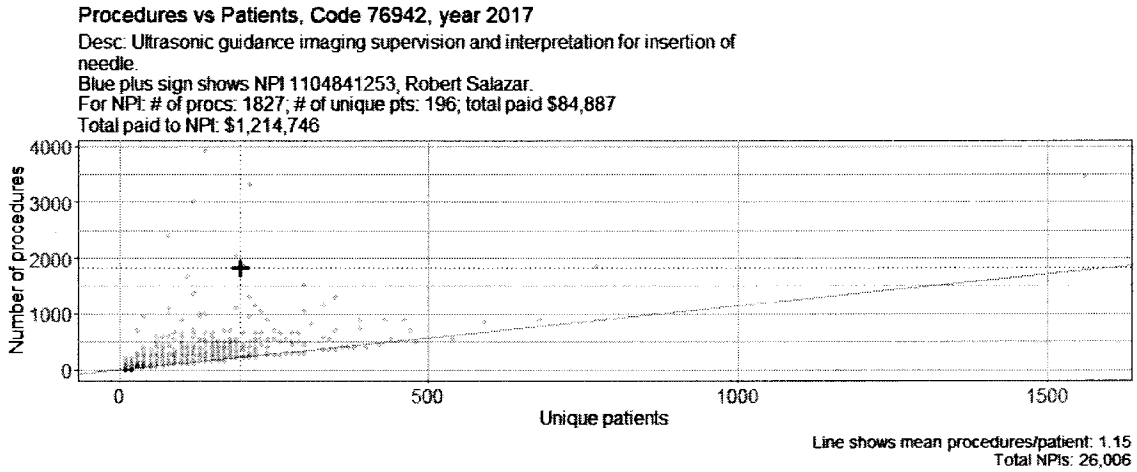
69. Ultrasound guidance imaging helps place needles deep within a patient at a site that is not visible. For example, ultrasonic guidance would be necessary in a hospital to remove fluid from a lung or a deep cyst that cannot be located visually.[5]

[5] https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=263&ncdver=3&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=BC%7cSAD%7cRTC%7cReg&PolicyType=Both&s=All&KeyWord=Ultrasonic+guidance&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=EAAAABAAAAAA&

70. Based on patient counts, the number of claims, and procedures per patient, it appears Defendant claims CPT 76942 whenever he claims 62368 and/or 62370.

year	procedures	patients	procedures per pt.
2014	2,113	241	8.8
2015	2,156	233	9.3
2016	1,899	216	8.8
2017	1,827	196	9.3

71. Defendant's national rankings for this procedure parallel his ranks for procedures 62368 and 62370. For example, in 2017 he was *number eight among the 26,006 NPIs* (Medicare Part B providers) who claimed ultrasonic guidance.



Year	Amt paid	National rank by: claims	amt. paid.
2014	$ 125,833	16	19
2015	104,855	7	6
2016	92,974	6	4
2017	84,887	8	8

72. The use of ultrasound guidance in conjunction with non-covered (unnecessary) CPTs 62368 and 62370 (or any unnecessary claim) would also be considered not medically necessary.

C. False Claims for Many E/M Claims, CPT 99214

73. Medicare pays for physicians' and for specific non-physician practitioners' medically necessary evaluation and management (E/M) services. Medicare Claims Processing Manual, Publication 100-04, Ch.12, §30.6.1. It is not medically necessary to perform and then bill for a higher level of evaluation and management service when professional knowledge and experience dictates a lower level of service. Manual at Ch. § 30.6.1.A.

74. CMS publishes an Evaluation and Management Services Guide as a refence tool which summarizes other CMS documents such as the 1995 Documentation Guidelines for Evaluation and Management Services and the 1997 Documentation Guidelines for Evaluation and Management Services.[6]

75. CPT 99214 is defined as "Established patient office or other outpatient, visit typically 25 minutes." However, a visit's duration is an "ancillary factor and does not control the level of service to be billed," Manual at § 30.6.1. Code 99214 is the second highest code for established patient office visits. It requires two of the three criteria: detailed history, detailed examinations, and moderate complexity decision-making.

76. Based on patient counts, the number of claims, and procedures per patient, it appears Defendant claims CPT 99214 whenever he claims 62368 and/or 62370.

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[6] *See CMS,* Evaluation and Management *Services Guide 8* (2017), available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/eval-mgmt-serv-guide-ICN006764.pdf . The 2014 version was cited in *United States* v. *Riverside Healthcare Assn.*, Docket No. 4:11cv109, 2015 U.S. Dist. LEXIS 37134, at *9 (E.D. Va. Mar. 23, 2015).

year	procedures	patients	procedures per pt.
2014	5.593	734	8
2015	5,228	685	8
2016	2,389	518	5
2017	5,157	581	9

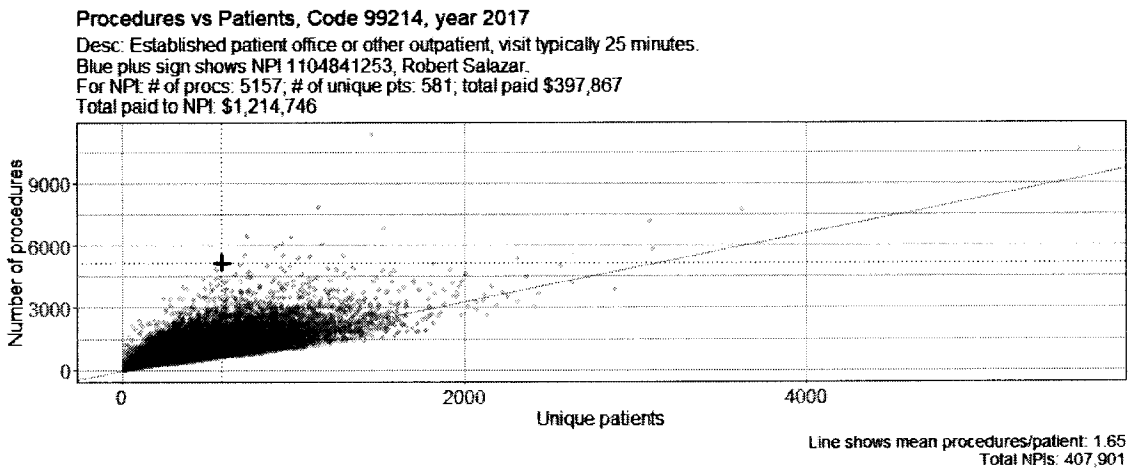
77. The correlation between claims for CPT 62370 refills and 99214 evaluation and management suggests that patients who returned to Defendant's office were routinely coded for 99214. This is medically unreasonable and unnecessary, even if the 62370 was medically reasonable and necessary.

78. Further, unlike most physicians who claim evaluation and management codes 99211 – 99215 based on their established patients' medical patients needs, Dr. Salazar claimed only code 99214, and claimed no codes 99211, 99212, 99213, or 99215.

79. By routinely charging 99214 when it was not medically necessary and reasonable, Dr. Salazar became one of the nation's top claimants for this procedure as measured by the number of claims he submitted and by the amount paid to him by the Government.

		National rank by	
Year	Amt paid	claims	amt paid.
2014	$ 457,269	11	9
2015	426,078	11	7
2016	195,529	863	625
2017	397,867	20	19

80. Except for 2016, Dr. Salazar ranked as one of the top claimants in the nation among the more than 400,000 healthcare providers who claimed code 99214 under Medicare part B.



IV. Relators Are an Original Source

81. The allegations or transactions herein were not "publicly disclosed," as that term is defined by the False Claims Act.

82. To the extent there were any qualifying public disclosures, Relators' allegations materially add to any data or information contained in any such public disclosures, which information it voluntarily provided to the Government prior to filing this action, so as to qualify as an "original source," as that term is defined by the False Claims Act.

83. CMS has disclosed 2014-2017 billing and reimbursement data through the "Medicare Provider Utilization and Payment Data: Physician and Other Supplier Public Use File" ("PUF"). This data is based on information from CMS's National Claims History Standard Analytic Files. It contains 100% final-action physician/supplier Part B non-institutional line items for the Medicare fee-for-service population.

84. Each year's PUF database contains more than 242 million entries relating to a single year's Medicare Part B claims. However, this raw data does not reveal the alleged frauds. In particular:

- It does not compare providers by amounts billed, amounts paid, procedures performed, or otherwise.
- It does not disclose medical relationships between procedures.
- It does not reveal procedures not performed that should have been performed.
- It does not compare a provider to "similar" providers.

85. Relators have not included this data in an exhibit. Each of the four years' 9+ million record Part B files would require approximately 27 million pages, more than 100 million pages together.

86. Because there is nothing inherently fraudulent with performing or billing for the procedures described herein, data resulting from this analysis and synthesis support these allegations but, by itself, this data did not "disclose" the allegations herein.

87. Similarly, there is nothing inherently fraudulent with outlier status as a top biller in a particular medical procedure. CMS reimburses healthcare providers for more than 6,000 HCPCS codes, almost all of which have many outliers, few of which represent frauds.

88. Accordingly, Relators converted raw data into information. Relator's research, investigation, analysis, and synthesis exposed frauds that the numbers alone do not. Relators' allegations based on medical experience further materially added to data contained in any such public disclosures.

V. Causes of Actions

89. This is a claim for refunds, treble damages, civil penalties and attorney's fees, under the Federal False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, and California Government Code §§ 12650 *et seq.*

A. Count I: Violations of 31 U.S.C. § 3729(a)(1)(A)

Relators repeats and realleges the paragraphs above as if fully set forth herein.

90. Defendant knowingly presented or caused to be presented false or fraudulent claims for payment or approval to Government Health Care Programs, all in violation of the federal False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

91. The United States paid said claims and has sustained damages because of these acts by Defendant.

B. Count II: Violations of 31 U.S.C. § 3729(a)(1)(B)

Relators repeat and reallege the paragraphs above as if fully set forth herein.

92. Defendant knowingly made, used, or caused to be made or used, false records or statements material to a false or fraudulent claim, all in violation of the federal False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

93. The United States paid said claims and has sustained damages because of these acts by Defendant.

C. Count III: California False Claims Act Violations

Relators repeat and reallege the paragraphs above as if fully set forth herein.

94. Defendant knowingly presented false and fraudulent claims for payment or approval to the State of California, and the payment of the false or fraudulent claims was a reasonable and foreseeable consequence of Defendant's statements and actions. Said claims were presented with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false. Cal. Govt. Code § 12651(a)(1)).

95. Defendant knowingly made, used, and caused to be made or used, false records or statements — i.e., the false certifications and representations made by Defendant when initially submitting the false claims for payments and the false certifications made by Defendant in submitting his cost reports — to get false or fraudulent claims paid and approved by the State of California. Defendant's false certifications and representations were made for the purpose of getting false or fraudulent claims paid, and payment of the false or fraudulent claims was a reasonable and foreseeable consequence of Defendant's statements and actions. Cal. Govt. Code § 12651(a)(2).

96. Defendant knowingly and improperly avoided his long-standing and continuing obligation to repay the wrongfully received and retained Medi-Cal funds to the State of California, in violation of the California False Claims Act, Cal. Govt. Code § 12651(a)(7).

97. The California State Government, unaware of the falsity of the records and statements and claims made, used, presented, or caused to be made, used, or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's unlawful conduct.

98. By reason of Defendant's acts, the State of California has paid money to Defendant upon the false, fictitious, or fraudulent claims described in this Complaint and has thereby suffered damages, been damaged, and continues to be damaged, in substantial amount to be determined at trial.

99. Additionally, the California State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

PRAYER

WHEREFORE, *Qui Tam* Plaintiff Relator Relators, for the United States, and for themselves, pray that judgment be entered against Defendant as follows:

- For each count, the amount of damages, trebled as required by law, and civil penalties up to the maximum permitted by law,
- For the maximum *qui tam* percentage share allowed by law and for attorney's fees, costs and reasonable expenses; and
- For any and all other relief to which Plaintiff may be entitled.

Plaintiff Relators request trial by jury.

/s/ Phillip E. Benson P.Benson 8/29/20
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